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PERMAN & GREEN 425 POST ROAD FAIRFIELD, CT 06824				
			EXAMINER WEISS JR, JOSEPH FRANCIS	
			ART UNIT 3743	PAPER NUMBER

DATE MAILED: 03/01/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/701,824

Applicant(s)

SINDERBY ET AL.

Examiner

Joseph F Weiss Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-59 is/are pending in the application.
- 4a) Of the above claim(s) 36-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims 36-59 drawn to an invention nonelected with traverse in Paper No. 6 or 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 13-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description does not disclose a neuro-efficiency parameter being derived from an inspiratory effort signal, but instead stipulates that it is derived from diaphragm EMGdi signal intensity correlated to lung volume. (See page 18 of the app.)

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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2. Claims 13-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant discloses an aspect of the invention to be deriving a neuro-efficiency parameter from a diaphragm EMGdi signal intensity correlated to lung volume signal, but does not claim this, instead claiming inspiratory effort compared to lung volume.

In regards to sub d of claim 24, applicant appears to be presenting structure, but only sets forth functional language, does applicant mean a "controller" and not just a control?

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 13-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younes (US 5107830).

In regards to claim 24, Younes discloses a ventilatory having a first input (P sub mus) for receiving a first signal representative of inspiratory effort and which would have an amplitude, a second input (Volume feed back see figs 7 & 9 and supporting text) for receiving a second signal representative of volume and which would have a second amplitude, a calculator which is fully capable of calculating a relationship between the first and second signals (pre-programmed electronics 22) that by dint of having the

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same empirical input data and structure is thus fully capable of calculating the ratio in a manner that falls within the ambit of neuro-ventilatory efficiency, and a control dependent on whether a present calculated value of said "neuro-ventilatory efficiency" is higher or lower than a past calculation of the "neuro-ventilatory efficiency" by an amount exceeding a given threshold (pre-programmed electronics 22) to then increase or decrease the ventilatory assist level. (See graphs and supporting text of figs 1-7)

In regards to claim 25, Younes discloses a calculator comprising a divider responsive to the ratios at predetermined intervals and a control comprising a comparator & adder (see the calculations that are the basis of the invention and which are pre-programmed into the electronics 22, col. 9 line 5 - col. 14 line 15, note prior claim rejection regarding the capabilities of the prior art to arrive at a value w/in the ambit of "neuro-ventilatory efficiency") wherein the adder is interposed between the comparator and the ventilatory assistance system.

In regards to claim 26, Younes discloses a calculator comprising a means for calculating said "neuro-ventilatory efficiency" relationship at predetermined intervals (note that the calculating means takes measurements over time and in relationship to respiratory events). (See col. 9 line 5- col. 14 line 15)

In regards to claim 27, the device of Younes discloses a calculator comprising a means for calculating said "neuro-ventilatory efficiency" relationship that is fully capable of doing so at intervals when one of said first and second amplitudes reaches a predetermined level. (See col. 9 line 5- col. 14 line 15).

In regards to claim 28, Younes's adder comprises a means for adding and a means for subtracting that is fully capable of adding or subtracting a preset increment or decrement when the presently calculated neuro-ventilatory efficiency is lower or higher than the past calculated value when the difference exceeds a threshold for the increment or decrement.

In regards to claim 29, A signal representative of a lung volume is inherently indicative of a given lung volume, thus the second signal of Younes discloses a second signal that is indicative of a given lung volume.

In regards to claim 30, A signal representative of inspiratory effort is inherently indicative of a given inspiratory effort, thus the first signal of Younes discloses a first signal that is indicative of a given lung volume.

In regards to claim 31, Younes discloses an alarm (col. 19 lines 27-32) that produces an alarm signal in response to deviations in signal data (note alarm activation in response to absence of a signal and also when lung pressure or volume is excessive) and hence would be fully capable of responding to deviations correlated to neuro-ventilatory efficiency when it exceeds a threshold amount.

In regards to claims 33 & 34, Younes discloses a means for expressing the first and second signals that is fully capable of expressing the signals as a mean, a median or a peak. (note electronics 22).

In regards to method claims 13-22, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow

from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 24-34.

Claims 20 & 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younes as applied to claims 13 & 24 above, and further in view of Ernst (US 3961627).

In regards to claim 32, Younes substantially discloses the instant application's claimed invention, but does not explicitly disclose a manual adjustment system to add/subtract a preset increment/decrement. However, Ernst discloses such (9). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Ernst and used them with the device of Younes. The suggestion/motivation for doing so would have been to give the operator additional control over the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claim 20, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claim 32.

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3. Claims 23 & 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younes as applied to claims 13 & 24 above, and further in view of Sackner (US 6015388).

Younes substantially discloses the instant application's claimed invention, but does not explicitly disclose deriving inspiratory effort from an EMG signal of at least one muscle of the subject. However, Sackner disclose such (Note use of diaphragm EMG in figs 1, EMGs of fig 2 and supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Sackner and used them with the device of Younes. The suggestion/motivation for doing so would have been to derive a more accurate indicator of inspiratory effort. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claim 23, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claim 34.



***Response to Arguments***

4. Applicant's arguments filed 29 Sep 03 have been fully considered but they are not persuasive.

Note that during patent prosecution claims are given their broadest reasonable interpretation and that while claims are read in light of the written description, limitations in the written description will not be read into the claims.

The examiner gives full faith and credit to applicant's assertions that the preliminary amendment submitted with his response was filed prior to the first office action. Thus, this action is made non-final. Non-finality is made for this reason, and only this reason and for no other reason.

**NOTE GENERALLY:**

5. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

6. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

**NOTE SPECIFICALLY:**

Applicant's assertion that the intended use label of "neuro-ventilatory efficiency representative parameter" as distinguishing, but in the apparatus claims such is not

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structure, thus it cannot serve as a positively claimed limiting structure, but a mere intended use/result and thus fails to distinguish over the prior art of record as applied.

In regards to the method claims, it is noted that nothing in regards to the derivation of the "neuro-ventilatory efficiency representative parameter" AS CLAIMED has nothing neurally related, but contrary to applicant's own written description takes non-neurally related data and somehow arrives at data that is then labeled as such. Only one claim touches on the source of data being neural (claims 23 & 35) yet under the doctrine of claim differentiation, the claims that these claims depend possess a greater scope regarding source of data that would encompass non-neurally derived data. Thus the method claims fail also to distinguish over the prior art of record as applied.

The examiner acknowledges that applicant has drafted a lengthy summary of what he feels Younes discloses and also failed to provide any comparison to applicant's disclosed invention in addition to failing to point out with particularity the novelty of applicant's invention. In response the examiner cites the reference of Younes for what it discloses and the above rejection for the proper interpretation of applicant's claimed invention during prosecution.

Other than explicitly set forth above, this office action does not include any acquiescence to any statement made by applicant.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6411843, 5520192, 5129390, 4986268, 4867152

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Aaron J. Lewis  
Primary Examiner

JFWeiss  
2/20/04